REMARKS:

In the Office Action dated August 13, 2009, claims 15-34, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 1-34 have been canceled and new claims 35-52 have been added to the application.

Claims 15-31 were rejected under 35 USC §112, first paragraph, as lacking an adequate written description. Claims 15-31 have been canceled and new claims added to the application which recite specific acetone insoluble components and supporting materials. In view of the above amendments, applicants request that this rejection be withdrawn.

Claims 15-31 were rejected under 35 USC §112, second paragraph as indefinite regarding the acetone insoluble phospholipid components. Claims 15-31 have been canceled and new claims have been added to the application which recite specific components. In addition, the new claims clarify that the acetone-insoluble phospholipid component is combined with the supporting material to produce a matrix incorporating ≥ 5 % by weight of the starting acetone-insoluble phospholipid component. In view of the above amendments, applicants request that this rejection be withdrawn.

Claims 15-31 were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-11, 13-21 and 23-37 of copending application serial no. 10/511,885. A terminal disclaimer is being prepared and will be filed shortly.

Claims 15-18 and 20-30 were rejected under 35 USC §102(e) as anticipated by Friedman. Applicants note that claim 19 was excluded from this rejection. Claims 15-30 have been canceled and new claim 35 includes the limitations of previous claim 19. In view of this

amendment, applicants contend that Friedman does not anticipate the presently claimed invention. Friedman discloses a homogeneous solid matrix comprising (a) at least 10% w/w of vegetable proteins, (b) lecithin and (c) at least one ingestible bioactive compound of at least low water solubility (Friedman, Abstract). The vegetable proteins are further defined in [0061]. The ingestible bioactive compound is selected from the group consisting of a drug, a nutrient, a vitamin, food supplement and mixtures thereof (Friedman, claim 12). Additives such as fumed silica may be added before or after drying in order to advance flowing properties of the resulting powder (Friedman, [0046]). The mixture may be extruded via wet granulation through a screen having openings of 0.5 mm to 2.5 mm as spheronized in a spheronizer (Friedman, [0058]).

The present invention differs from Friedman in that the matrix of the invention only consists of the supporting material and the acetone insoluble phospholipid which is the bioactive component. Further components such as the ingestible bioactive compound as disclosed by Friedman are not included in the matrix of the present invention. In the present invention, the phospholipid serves as the bioactive compound. Thus, Friedman does not describe a hard matrix which consists only of phospholipids and supporting materials and which further shows the dimensions and the respective amounts of bioactive component as indicated in new claim 35. In view of the above amendments and explanations, applicants request that this rejection be withdrawn.

Claims 15-18 and 20-31 were rejected under 35 USC §103(a) as unpatentable over Kiliaan in view of Friedman. Applicants note that claim 19 was excluded from this rejection. Claims 15-30 have been canceled and new claim 35 includes the limitations

of previous claim 19. In addition, applicants respectfully point out that Kiliaan et al. disclose a nutritional preparation suitable for the prevention and/or treatment of vascular disorders comprising (a) long-chain polyunsaturated fatty acids, (b) phospholipids and (c) compounds which are a factor in methionine metabolism, e.g. folic acid, vitamin B12, vitamin B6, magnesium and zinc (Kiliaan, Abstract). The Office Action refers to the capsule according to Example 1 consisting of ten different ingredients, inter alia, phospholipids, fatty acids, vitamins as well and folic acid. Kiliaan discloses formulations necessarily containing a factor in methionine metabolism and long-chain polyunsaturated fatty acids. However, these components are excluded from the presently claimed invention. In view of the above amendments and comments, applicants request that this rejection be withdrawn.

Claim 19 was rejected under 35 USC §103(a) as unpatentable over Kiliaan in view of Friedman, further in view of Ponroy. Ponroy discloses a method of regulating melatonin secretion in warm-blooded animals comprising administering an amount of phospholipids having a high content of long-chain unsaturated fatty acids derived from animal brains or hen's eggs (claim 1). The phospholipids are combined with non-toxic pharmaceutically acceptable excipients, extenders or inert carriers in order to make pharmaceutical and/or dietetic compositions for oral or parenteral administration (Ponroy, column 2, lines 30-33). None of the Examples in Ponroy et al. disclose the matrix of the present invention consisting only of phospholipids and a supporting material. As pointed out in the description on page 3, 2nd paragraph, of the present application, the object of the present invention is to provide a physiologically compatible matrix having an increased phospholipid amount so that a physiologically

effective amount of the bioactive phospholipids can be administered in a suitable dosage form, e.g. as an average-sized tablet. Moreover, the known problems regarding the degradation of the phospholipids had to be addressed. The present inventors have surprisingly found that the matrix according to the invention significantly increases compliance due to the convenient size of the matrix (page 3, last paragraph). In addition, the stability of the phospholipid component is increased by the specifically defined matrix as compared to the comparative formulations (page 3, last paragraph and Table on page 12). None of the cited references individually or in combination suggests or discloses a matrix consisting only of a phospholipid and a support material. In contrast to the present invention, in the prior art references, the phospholipid component is used as an *adjuvant* in pharmaceuticals containing a drug (Friedman), or compounds which are factors in methionine metabolism (Kiliaan et al.) (see also page 1 bridging page 2 of the application), but not as the sole bioactive component. In view of the above amendments and discussion, applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 35-52 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By 

Monica Chin Kitts
Attorney for Applicant
Registration No. 36,105
ROTHWELL, FIGG, ERNST & MANBECK
1425 K. Street, Suite 800
Washington, D.C. 20005
Telephone: (202) 783-6040

MCK/cb